



# Pfizer Announces Positive Top-Line Results from REFLECTIONS B537-02 Study for PF-06438179 (infliximab-Pfizer) a Potential Biosimilar to Remicade® (infliximab)

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Results confirm similar efficacy of PF-06438179 (infliximab-Pfizer) to Remicade® (infliximab), in combination with methotrexate

Pfizer Inc. (NYSE:PFE) announced the confirmatory study (REFLECTIONS B537-02) evaluating the efficacy, safety, and immunogenicity of PF-06438179 (infliximab-Pfizer) compared to Remicade® (infliximab) met its primary endpoint. The trial demonstrated equivalent efficacy of the proposed biosimilar PF-06438179 to the originator product as measured by the American College of Rheumatology 20 (ACR20) response at Week 14. PF-06438179 is being developed as a potential biosimilar to Remicade.

## About REFLECTIONS B537-02

REFLECTIONS B537-02 is a Phase 3, multi-national, randomized, double blind, two-arm, parallel group study designed to evaluate the safety, efficacy, and immunogenicity of PF-06438179 (infliximab-Pfizer) versus Remicade in combination with methotrexate when administered intravenously to treat patients with moderate to severely active rheumatoid arthritis (RA) who have had an inadequate response to methotrexate therapy. This study is also designed to evaluate clinical response, safety and immunogenicity after study drug transitioning from Remicade to PF-06438179 after 30 or 54 weeks of Remicade treatment. The primary endpoint is ACR20 response ( $\geq 20\%$  improvement by ACR criteria)

at Week 14 of study treatment. Evaluation at both earlier time points (Weeks 2, 4, 6, 12) and later time points (Weeks 22 and 30) will be used to support the primary endpoint analysis. More information about the PF-06438179 REFLECTIONS B537-02 study can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

#### About PF-06438179 (infliximab-Pfizer)

PF-06438179 (Infliximab-Pfizer) is a chimeric human-murine monoclonal antibody (mAb) against tumor necrosis factor (TNF) that is currently in development as a potential biosimilar for all currently approved indications of Remicade (infliximab).

Remicade is currently approved in the US and EU for rheumatoid arthritis (RA), Crohn's disease, pediatric Crohn's disease, ulcerative colitis, pediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis. Biosimilarity has not yet been established by regulatory authorities and is not yet claimed. PF-06438179 is an investigational compound and has not received regulatory approval in any country.

In February 2016, Sandoz acquired the rights from Pfizer for the development, commercialization and manufacture of PF-06438179 in the 28 countries that form the European Economic Area (EEA). Under the terms of the divestment, Pfizer retains commercialization and manufacturing rights to PF-06438179 (a proposed biosimilar to Remicade) in countries outside the EEA.

#### About Pfizer: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. For more information, please visit us at [www.pfizer.com](http://www.pfizer.com). In addition, to learn more, follow us on Twitter at @Pfizer and @Pfizer\_News, LinkedIn, YouTube and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

DISCLOSURE NOTICE: The information contained in this release is as of September 16, 2016. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments. This release contains forward-looking information about PF-06438179, including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; whether and when any applications for PF-06438179 may be filed with regulatory authorities in any jurisdictions; whether and when regulatory authorities in any such jurisdictions may approve any such applications for PF-06438179, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; intellectual property and/or litigation implications; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of PF-06438179; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2015, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 10-Q and Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

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